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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,792	11/16/2000	Mary Collins		3965

7590 02/07/2003

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EXAMINER

HAMUD, FOZIA M 13

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/714,792

Applicant(s)
COLLINS et al.

Examiner
Fozia Hamud

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 24, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 38-45 is/are pending in the application.
- 4a) Of the above, claim(s) 38-40 and 42-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election of the invention of Group II (claims 18 and 41) in Paper No.12, filed on 04 December 2002 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP. § 818.03(a)).

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 38-40, 42-45 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Specification

2a. It is noted that this application is a continuation of 08/846,344, filed on 04/30/1997 now "U. S. Patent No. 6,268,480", which is a divisional of Application 08/609,572 filed on 03/1/1996, now "U.S Patent No. 5,710,023". Instant specification only lists that this application is a continuation.

2b. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

2c. On page 5, line 19 of the instant specification, a referral to a "claim 11" is made, however, claim 11 has been canceled in the preliminary amendment filed on 11/16/00 in Paper No:4. Appropriate correction is required.

Claim objections:

3. Claims 18 and 41 are objected to because of the following informalities: Claims 18 and 41 recite non-elected inventions, i.e SEQ ID NO:2 and fragments thereof.

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Claim rejections-Double patenting

Non-statutory double patenting rejection (obviousness-type)

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4a. Claim 41 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,248,714. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 41 in the instant application is drawn to a method inhibiting the binding of IL-13 to IL-13 receptor in a mammalian subject by administering a therapeutically effective amount of a composition comprising an antibody which specifically reacts with an isolated IL-13bc protein of SEQ ID No:4, or to an isolated IL-13bc

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protein which comprises amino acid 26 to 341 or 363 to 380 of SEQ ID NO:4. Claim 1 U.S. Patent No. 6,248,714 (having one common inventor with the instant application), is drawn to a method inhibiting the binding of IL-13 to IL-13 receptor in a mammalian subject by administering a therapeutically effective amount of a pharmaceutical composition comprising a protein of SEQ ID NO:4, or a protein which comprises the amino acid sequence from amino acid 26 to 341 or 363 to 380 of SEQ ID NO:4. Instant claim 41 is obvious from claim 1 of the patent, because they are both drawn to a method of inhibiting the binding of IL-13 to its receptor. IL-13 receptor is a heterodimer that is composed of IL-4 receptor α chain and IL-13 binding chain, and IL-13 binds to IL-13 bc with relatively high affinity. Therefore, it would have been obvious to one skill in the art to use an antibody that binds to the binding chain portion of the IL-13 receptor to inhibit the binding of IL-13 to its receptor, because IL-13 would not bind to its receptor in the absence of the IL-13 bc. Allowance of the pending claim, would have the effect of extending the enforceable life of the allowed claim beyond statutory limit

Claim rejections-35 USC § 112

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 18 and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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5a. Claim 18 is drawn to a composition comprising an antibody that specifically reacts with a protein comprising a specific amino acid sequence, and claim 41 is drawn to “a method inhibiting the binding of IL-13 to IL-13 receptor in a mammalian subject by administering a therapeutically effective amount of a composition *comprising* an antibody which specifically reacts with an a protein comprising a specific amino acid sequence”. Because of the “comprising language”, the claims encompass an antibody which binds to an epitope that is not contained within the recited specific amino acid sequences. It is well known in the art the portion of a protein to which an antibody binds usually consists of no more than six to eight amino acid residues. It is also well known in the art to express a recombinant protein as a part of a fusion protein “comprising”, in addition to the desired amino acid sequence, an antigenic tail such as “FLAG epitope”, “a polyhistidine tail”, or a protein A fragment to facilitate the purification of the desired protein. Because of the presence of the term “comprising” in instant claim 18, the claim encompasses any antibody which can bind to any epitope which can be expressed as a portion of the desired specific amino acid sequences. Therefore, claim 18 encompasses any antibody which can bind to any polypeptide or protein and claim 41 encompasses a method of administering an antibody which can bind to any polypeptide or protein. The instant specification, however, does not provide a written description or the guidance needed to produce an antibody which binds to any epitope which is contained within the recited sequences.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6a. Claims 18 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6b. Claims 18 and 41 are vague and indefinite because the claims recite "...specifically reacts with ...", however, it is unclear how does the claimed antibody react with the recited protein. Does this mean that the claimed antibody reacts with the recited protein in a manner different than binding to said protein? If so, how? Appropriate correction is required.

Claim rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Hopp et al (U.S. Patent 5,011,912).

Hopp et al disclose an antibody which binds DYKDDDDK peptide, (column 4, lines 51-65 and claims 2 and 3). Hopp et al's reference anticipates instant claim 18, because the claim encompasses an antibody which binds to any antigenic peptide (see section 3a of this office action), including the flag epitope DYKDDDDK which was bound by the antibody disclosed by Hopp et al.

Conclusion

8. No claim is allowed.

Advisory Information

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
03 February 20023


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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